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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/114,844	07/14/1998	AVI J. ASHKENAZI	1129R1	9726

7590

07/15/2005

GENENTECH, INC.

1 DNA WAY

SOUTH SAN FRANCISCO, CA 94080-4990

EXAMINER

KAUFMAN, CLAIRE M

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/114,844	Applicant(s) ASHKENAZI ET AL.	
	Examiner Claire M. Kaufman	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14,29,34,35 and 38-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14,29,34,35 and 38-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/6/05 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-6, 8-14, 29, 38-45, 47-55, 57 and 58 remain rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al. (US Patent 6,214,580) for the reasons set forth in the previous Office action (mailed 4/8/04) on page 2.

Applicants' arguments directed to the rejection under 35 U.S.C. 102(e) are directly applicable to the rejection under 35 USC 103 and are addressed below. Note that in both rejections in previous Office actions, the US patent number in parenthesis was previously incorrect, although the number of the Ni et al. patent listed on the PTO-892 form (mailed 7/12/01) accompanying the original rejection was correct. Further, Applicants have correctly identified the provisional applications of the patent relied on in the rejections.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14, 29, 34, 35 and 38-58 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al. (US Patent 6,214,580) for the reasons set forth in the previous Office action (mailed 4/8/04) on page 2.

Applicants' arguments addressing the rejections under 35 USC 102 and 103 are the same as previously set forth (see responses filed 1/31/02, pages 8-11; 6/2/03, pages 6-7; and 1/27/04, p. 3). Applicants argue that priority to provisional 60/050,936 should not be granted for US 6,214,580 because the priority application does not meet the requirements under 35 USC 112, first paragraph, and because of the unpredictable nature of this field of technology. It is argued that in provisional application 60/050,936, the identification of a ligand for the TR10 receptor was purely prophetic, and the action attributed to the receptor, *i.e.*, induction of apoptosis upon receptor activation, was incorrect. These facts combined with unpredictability in this field of technology support denial of priority for the provisional application of the patent relied upon in the rejection under 35 USC 102(e) and 103(a). The arguments have been fully considered, but remain not persuasive for the reasons of record. It is maintained that the patent's priority documents meets the written description and the enablement requirement because each teaches the protein (TR10) and encoding nucleic acid, as well as how to make and use the protein relied

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upon as prior art. Disclosure of TRAIL as the ligand for TR10 receptor is sufficient for use of the receptor. Even though the patent's specification refers to the varied effects of the TNF family of ligands and receptors, and even though the TRAIL ligand identified as the ligand for TR10 was not confirmed by experimentation in the earliest provisional, 60/050,936, the specification's assertion was correct. As stated in previous Office actions, a working example showing TRAIL ligand binding is not required and a prophetic statement is sufficient if correct. Despite incorrectly stating the activity of TR10 caused induction of apoptosis (Example 5 of 60/050,936), only a single enabling use is required for the patent to receive benefit of priority to 60/050,936. Therefore, the use of TR10 as a receptor that binds TRAIL in combination with the sequence of TR10 is sufficient to grant priority to the earliest filed provisional application of US 6,214,580. It is noted that the functional limitations in the instant application's claims (*e.g.*, claim 1, lines 4-5) are an inherent property of the receptor polypeptide of the prior art.

Applicants argue that an interference cited in Applicants' response between two application unrelated to the instant application supports the denial of priority to provisional application 60/050,936 of US 6,214,580. The argument has been fully considered, but is not persuasive. The interference proceeding has not been published and is not precedential. The Examiner is not permitted to comment of the prosecution of applications unrelated to the instant application.

Conclusion

This is a continuation of Applicant's earlier Application No. 09/114,844. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571) 272-0873. Dr. Kaufman can generally be reached Monday, Tuesday and Thursday from 9:00AM to 3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (571) 272-0829.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

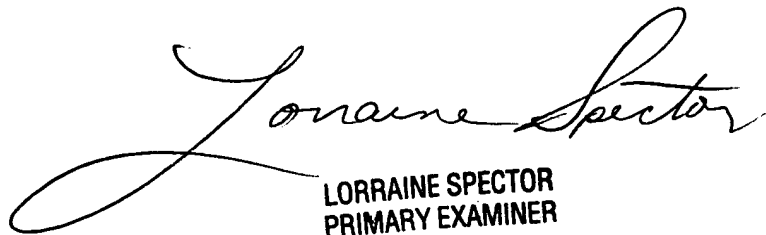
Official papers filed by fax should be directed to (571) 273-8300. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

July 11, 2005



LORRAINE SPECTOR
PRIMARY EXAMINER